Gregg L. Weiner
Stephen S. Rabinowitz
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One New York Plaza
New York, New York 10004-1980
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Attorneys for Plaintiff

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

KERYX BIOPHARMACEUTICALS, INC.	:	ECF CASE
Plaintiff,	:	07 Civ. 10376 (CSH)
- against -	:	**DECLARATION OF WILLIAM J. BENNETT**
PANION & BF BIOTECH, INC.,	:	
Defendant.	:	

1. I am Vice President and Director of Pharmaceutical Development and Manufacturing at Keryx Biopharmaceuticals, Inc. ("Keryx"). I have held that position since May 2003, when I first joined Keryx. I make this declaration in support of Keryx's motion for a preliminary injunction. I have personal knowledge of the matters stated in this declaration, except as otherwise stated.

2. I am responsible for the pharmaceutical development of the technical products, i.e., Drug Substance (API) and Drug Product, which is often referred to as Chemistry, Manufacturing and Controls ("CMC"). In this role I am responsible for ensuring the development and manufacture of drugs for clinical trials, submitting the CMC portion of regulatory dossiers to the federal Food and Drug Administration ("FDA") or foreign Regulators, and handling questions from Regulators regarding quality, production, sourcing of raw materials, etc.

3. Prior to joining Keryx, and from 1984, I was responsible for development, scale up and support of manufacturing for animal drugs and agricultural products at American Cyanamid, which was purchased in 1994 by American Home Products (now Wyeth Pharmaceuticals). In this position, I was responsible for development, scale up and manufacture for at least fourteen different products, including specialty intermediates. I was also responsible for developing and approving plant design and supporting start-ups worldwide, either at contract manufacturers and at owned-plants. In this capacity I also had oversight of the collection and submission of data for the FDA, the Environmental Protection Agency, the European Medicines Agency, the Japanese Ministry for Health, Labor and Welfare, the Japanese Ministry for Forestry and Fisheries and other regulatory bodies worldwide.

4. I actively supported drug regulatory submissions in Europe and Japan as well as in the U.S. during my career with Wyeth Pharmaceuticals, including the collection and submission of data, design and implementation of quality controls and equipment and process validation, and preparation for and participation in FDA and EU audits.

5. My roles and experience at Keryx have covered similar functions and responsibilities to my previous experience. As a result of my experience, I am very familiar with the process of obtaining marketing authorizations from the FDA in the United States and have a working understanding of the equivalent processes in other jurisdictions.

Overview of CMC Development

6. CMC development occurs concurrently with the clinical trials and toxicology studies that are needed for drug approval, and includes the following phases:

(i) **Phase I.** The Drug Substance and Drug Product must be characterized and shown to be free of significant impurities and stable over the period of the study. Analytical methods must be shown to be suitable for the purpose and the manufacturing process must be clearly defined. In the case of ferric citrate, the Drug Substance -- also known as Active Pharmaceutical Ingredient ("API") -- is a powder. The Drug Product contains the Drug Substance (API) in a form suitable for administration to patients, such as a capsule or a tablet if the drug is to be taken orally.

(ii) **Phase II.** Analytical methods must be shown to be capable of validation and a manufacturing process should have been developed which can be run on commercial scale to reproducibly produce Drug Substance and Drug Product within the specified quality parameters. At this point the "boundaries" of the product and production are typically established and should not change significantly through the NDA submission and approval process.

(iii) **Phase III.** This is the most critical phase for CMC, since it must develop data and technology to address the elements which are critical to an acceptable NDA package, and includes the following major elements. All issues raised by the FDA (or other Regulator) must be addressed with respect to characterization of the product, analytical methodology, and steps necessary to

guarantee quality in production and storage, etc. Typically during this phase, the FDA (or other Regulator) will highlight methodologies or specifications which may be inadequate for approval. All specifications and methods will need to be consistent with published guidance and current best practice. Prior to approval of the NDA , the manufacturing process and selected sites manufacturing and handling Drug Substance and Drug Product will be need to be accepted by the FDA. The equipment and process must be validated and the shelf life of the product manufactured at the commercial scale will be established based on stability data from three consecutive near commercial scale batches.

(iv) **Phase IV.** This phase includes the development of new formulations, considerations regarding extended shelf life, compatibility with other drugs, etc.

CMC Development Activities By Keryx's Contractors

7. In developing ferric citrate as a pharmaceutical product, Keryx works with a number of outside contractors, including BRI Pharmaceutical Research, Inc. ("BRI") in Vancouver, Canada, which was introduced to Keryx by Panion. BRI, in turn, introduced Keryx to BioVectra DCL ("BioVectra") in Prince Edward Island, Canada, and [through BioVectra to] the PharmPro Services division of Fluid Air, Inc. ("PharmPro"), which is located in Aurora, IL among other places.

8. Keryx's development work for ferric citrate may be divided into two categories. The first category concerns work that is undertaken to generate information that is needed for commercialization and approval, but that does not result in Keryx being supplied with ferric citrate. The second category concerns

work that results in Keryx being supplied with ferric citrate, for use in critical toxicology testing (in animals) and in human clinical trials undertaken to prove that ferric citrate is safe and effective for therapeutic use.

9. The first category of information-generating work includes:

(i) process improvements to find cheaper and more efficient processes for manufacturing pharmaceutical-grade ferric citrate. This involves initial feasibility testing of alternative process conditions or alternative process steps, followed by directed exploratory work and -- if the results are sufficiently promising -- a formal process qualification trial. Drug Substance (API) that is manufactured in the course of this process improvement work is not used for clinical trials or critical toxicology studies, because it would not have been manufactured in accordance with the applicable regulatory controls and prior approvals necessary to meet Good Manufacturing Process (GMP) requirements.

(ii) developing the specifications and quality control tests for the CMC submission to the FDA or other Regulator, including criteria and tests to ensure the purity of the Drug Substance and relevant properties of the Drug Compound such as potency, appearance, and time to dissolve when ingested. Any change in the manufacturing process may require adapting the specifications and quality control tests in order to ensure that the modified process is properly understood and controlled, and to verify the quality and stability of the resulting product.

(iii) improvements to the dosage form of the product to make it more palatable to patients and to promote stability and convenience of use. Since the

Drug Substance or API is used to make the Drug Product, changes in the manufacturing process or specifications of the API will need to be evaluated by testing the quality attributes, including stability, of the Drug Product subsequently made from it.

10. All the activities currently being performed for Keryx by BRI, BioVectra and PharmPro fall into the first category of information-gathering development work that provides Keryx with information needed for drug development but does not result in Keryx being supplied with ferric citrate Drug Substance (API) or Drug Product.

11. The CMC development activities that Keryx is performing with the help of outside contractors, including BRI, BioVectra and PharmPro, are essential to successful development of ferric citrate as a pharmaceutical product. Interruption of these CMC development activities would inevitably delay the date on which Keryx could obtain regulatory approval to launch ferric citrate as a pharmaceutical product.

Interactions Between Keryx And Panion In Developing Ferric Citrate

12. I have been principally responsible for coordinating Keryx's interactions with Panion concerning the development of ferric citrate as a pharmaceutical product. On July 26, 2006, Keryx advised Panion that Keryx urgently needed 100 kg of ferric citrate Drug Substance (API) for use in toxicology studies. See Exh. 1 (email dated July 26, 2006 from W. Bennett to M. Chiang). In response, Panion introduced Keryx to BRI (Panion's previous contractor) for the purposes of organizing supply but then declined to participate in any planning, saying

that it simply wished to be kept informed. (Exh. 2, email dated August 14, 2006 from C. Chiang to D. Kwok). Keryx kept Panion informed of its development program by emails and progress reports, and invited Panion to meetings with BRI, which Panion declined to attend on the grounds that "Panion is a small company with limited budget and resources." (Exh. 3, email dated October 26, 2006 from C. Chiang to W. Bennett).

13. In August, 2006, Panion asked BRI to obtain a quote for producing 400 kg of ferric citrate API. (Exh. 4, email dated August 15, 2006 from C. Chiang to W. Bennett) Later that same month, BRI emailed BioVectra's quote to Keryx with a copy to Panion. (Exh. 5, email dated August 24, 2006 from C. Faan to W. Bennett with c.c. to C. Chiang).

14. When Keryx repeated its urgent request for ferric citrate API, and asked Panion to supply even a small quantity (5 kg) immediately (See Exh. 6, email from W. Bennett to C. Chiang, dated August 28, 2006), Panion replied that it had "checked the inventory and found out we don't have any quantity in stock." (Id., email from C. Chiang to W. Bennett dated September 1, 2006).

15. Upon receipt of this information, on September 5, 2006, I placed a purchase order with BioVectra for the manufacture of 400 kg of API, in 3 lots, under that quotation. On September 11, 2006, I emailed Panion stating that I was planning to manufacture "a large pre[aration] of Fe[rric] Citrate" and offering to increase that order to accommodate "any API needs [that Panion might have] for the next several months." (Exh. 7, email dated September 11, 2006 from W. Bennett to C. Chiang). Without objecting to Keryx's order or offering to take over the work of coordinating

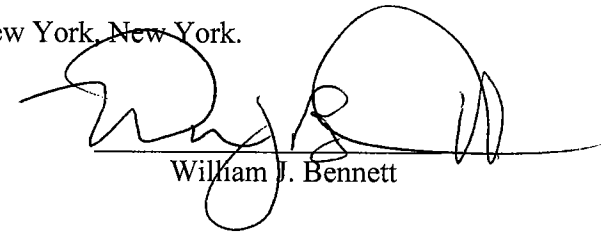
the production, Panion responded that it had sufficient API for its own purposes. After receiving Panion's response, Keryx ordered a fourth batch of API from BioVectra.

16. After ordering the fourth batch, and before production began, I again referred Panion to Keryx's forthcoming "production at BioVectra." (Exh. 8, email from W. Bennett to C. Chiang, dated between October 17 and October 25, 2006). Despite its awareness of Keryx's order for production by BioVectra, Panion did not object or offer to participate in any active way.

17. Panion continued to be copied on emails periodically over the coming month and a half until production began, and then over the subsequent two months on discussions of changes in specifications and controls. When production of ferric citrate Drug Substance (API) was complete, including the new (fourth) batch, Panion wrote acknowledging its awareness that "Keryx, with the Panion subcontractor BRI help, has manufactured a new batch of drug substance" and asking Keryx to provide "the final executed batch records and final specifications for the newly manufactured batch so that we can file the updated information to update the D[rug] M[aster] F[ile] . . . ." (Exh. 9, email dated July 30, 2007 from C. Chiang to T. Mason with c.c. to W. Bennett). Even at this time, Panion raised no objection to the fact that Keryx had organized the production and paid for it directly. The four lots of API have been manufactured and title has passed to Keryx. The batch records and specification changes have been provided to Panion.

I, WILLIAM J. BENNETT, hereby declare under penalty of perjury under the laws of the United States that the foregoing is true and correct to the best of my knowledge and belief.

Executed this 20th day of November, 2007 at New York, New York.



William J. Bennett

559756.1

Exhibit 1
to Declaration of William J. Bennett

From: Cindy Chiang [cchiang@pbf.com.tw]
Sent: August 15, 2006 4:22 AM
To: wbennett@keryx.com; cfaan@bripharm.com; tmason@keryx.com
Cc: 'Winston Town'; rniecestro@keryx.com; kchan@globoasia.com; khoberman@keryx.com; michaelchiang@pbf.com.tw; cchiang@globoasia.com; 'David Kwok'
Subject: RE: Urgent request for Ferric Citrate API
Dear Bill, Dear Clara

1. BRI will obtain quote for 400Kg from BioVectra and will revert.
2. Panion will also check our inventory balance of clinical materials.
3. Panion is willing to pay for the 1st hour of the consultation charge. Please understand that Panion is a small company and we do not have the resources to extend beyond this.

Thank you and regards,

Cindy Chiang
Panion & BF Biotech Inc
Phone: (02) 26558218 ext 302
Fax: (02) 26558318
Email: cchiang@pbf.com.tw

From: wbennett@keryx.com [mailto:wbennett@keryx.com]
Sent: Monday, August 14, 2006 10:32 PM
To: Cindy Chiang
Cc: Winston Town; rniecestro@keryx.com; tmason@keryx.com; cfaan@bripharm.com; David Kwok; kchan@globoasia.com; khoberman@keryx.com; michaelchiang@pbf.com.tw
Subject: RE: Urgent request for Ferric Citrate API

Sorry Cindy, that would be 400 kg!

We need 40 kg to start the toxicity studies.

Regards

Bill

From: Bennett, William J. [wbennett@keryx.com]
Sent: Monday, August 14, 2006 9:41 AM
To: 'Cindy Chiang'
Cc: 'Winston Town'; Niecestro, Robert [rniecestro@keryx.com]; Mason, Tim [tmason@keryx.com]; cfaan@bripharm.com; 'David Kwok'; kchan@globoasia.com; Hoberman, Ken [khoberman@keryx.com]; michaelchiang@pbf.com.tw
Subject: RE: Urgent request for Ferric Citrate API

Dear Cindy

Thank you for your response and the introduction to BRI. Tim Mason, my Director of API Process Development will be the lead on that project. Please obtain a formal quotation for production of 4 kg.

We would like to understand some of the specifications more clearly -- who could we talk to about that?

Finally, I would greatly appreciate it if you could provide some API from your inventory to start toxicity testing that is related to completing phase 2 requirements. We need to do this before we can enter phase III. Can you check please and advise what might be available?

Best Regards

Bill

From: Cindy Chiang [mailto:cchiang@pbf.com.tw]
Sent: Monday, August 14, 2006 9:26 AM
To: Bennett, William J. [wbennett@keryx.com]; michaelchiang@pbf.com.tw; Hoberman, Ken [khoberman@keryx.com]
Cc: 'Winston Town'; Niecestro, Robert [rniecestro@keryx.com]; Mason, Tim [tmason@keryx.com]; 'Cindy Chiang'; cfaan@bripharm.com; 'David Kwok'; kchan@globoasia.com
Subject: RE: Urgent request for Ferric Citrate API

Dear Bill,

To facilitate your CMC development, I here, under separate email, introduce you to BRI, contents of which are self explanatory. Please find an indicated quotation obtained from Biovectra/BRI in February 2006. If this is in line with your current thinking, we will obtain formal quotation from Biovectra/BRI

Best regards,

Cindy Chiang
Panion & BF Biotech Inc
Phone: (02) 26558218 ext 302
Fax: (02) 26558318
Email: cchiang@pbf.com.tw

From: wbennett@keryx.com [mailto:wbennett@keryx.com]
Sent: Wednesday, July 26, 2006 1:20 AM
To: michaelchiang@pbf.com.tw

Cc: Winston Town; cindy chiang; khoberman@keryx.com; rniecestro@keryx.com; tmason@keryx.com
Subject: Urgent request for Ferric Citrate API

Dear Michael

You should receive your payment by wire very shortly -- Ken Hoberman is coordinating.

Once the account is settled, I would like to proceed ASAP on procurement of API.

At our recent meeting with the FDA, they indicated that we will not have fulfilled our Phase 2 requirements with this compound until three studies are performed -- which will require up to 100 kg of API in total. We want to complete this work ASAP since until we complete these Phase 2 requirements, we cannot begin our Phase 3 work.

Would you please tell me if you have API in inventory that you could transfer to us under the cost conditions of the contract? Even if you do not have the full quantity, at least we could start the longer studies.

Finally, further to my note early in the month to Cindy -- I would also like to advance the production of several batches as well with BRI. How would you like to handle these arrangements? Shall I contact BRI directly or would you like us to work jointly on the project?

Thanks and Best Regards

Bill

Exhibit 2
to Declaration of William J. Bennett

-----Original Message-----
From: Cindy Chiang [mailto:cchiang@pbf.com.tw]
Sent: August 14, 2006 6:22 AM
To: 'David Kwok'; 'Clara Faan'; khoberman@keryx.com; wbennett@keryx.com
Cc: kchan@globoasia.com; 'Winston Town'; michaelchiang@pbf.com.tw; 'Cindy Chiang'
Subject: Introduction of Panion's partner on ferric citrate project

Dear Dave, Dear Clara,

This is Cindy Chiang of Panion & BF Biotech. We wish to take this opportunity to inform you that we have entered a licensing agreement with Keryx Biopharmaceuticals of New York. Under the terms of the agreement, Keryx will be responsible for further clinical development of Ferric Citrate in North America and certain territories. However, Panion is still responsible for the API. Therefore, any issues regarding API will need to consult with Panion. Under the clinical development, Keryx will need to understand more on the CMC development. The responsible person from Keryx is Mr. Bill Bennett and he should be in touch with you shortly. Please also note that Panion will not be involved in the dialogue, but please do keep us informed. Any amendment and changes of API will need to be agreed upon by Panion. In addition, any charges will also be agreed in advance by Panion. If you have any question, please feel free to contact me.

Best regards,

Cindy Chiang
Panion & BF Biotech Inc
Phone: (02) 26558218 ext 302
Fax: (02) 26558318
Email: cchiang@pbf.com.tw

Exhibit 3
to Declaration of William J. Bennett

From: Cindy Chiang [mailto:cchiang@pbf.com.tw]
Sent: Thursday, October 26, 2006 5:02 AM
To: Bennett, William J. [wbennett@keryx.com]; 'Clara Faan'
Cc: bobcatw@comcast.net; 'Daniel Gold'; 'David Kwok (BRI)'; 'Winston Town (GBA)'; michaelchiang@pbf.com.tw; Mason, Tim [tmason@keryx.com]
Subject: RE: Draft of proposed specification changes for ferric citrate

Dear Bill,

Thanks for the information and inviting us to the meeting. Panion will not attend this meeting, but please do keep us informed of the discussion result and proposal of changes. In principle, Panion will try its best effort to facilitate the development of Keryx's side to make the project moving forward. However, please kindly understand that Panion is a small company with limited budget and resources. We need to discreetly consider all the changes that will incur additional cost.
Once we receive the discussion result/proposal of changes, we will respond back as soon as possible. Thank you.

Warm regards,

Cindy Chiang
Panion & BF Biotech Inc
Phone: (02) 26558218 ext 302
Fax: (02) 26558318
Email: cchiang@pbf.com.tw

Exhibit 4
to Declaration of William J. Bennett

From: Cindy Chiang [cchiang@pbf.com.tw]
Sent: August 15, 2006 4:22 AM
To: wbennett@keryx.com; cfaan@bripharm.com; tmason@keryx.com
Cc: 'Winston Town'; rniecestro@keryx.com; kchan@globoasia.com; khoberman@keryx.com; michaelchiang@pbf.com.tw; cchiang@globoasia.com; 'David Kwok'
Subject: RE: Urgent request for Ferric Citrate API
Dear Bill, Dear Clara

1. BRI will obtain quote for 400Kg from BioVectra and will revert.
2. Panion will also check our inventory balance of clinical materials.
3. Panion is willing to pay for the 1st hour of the consultation charge. Please understand that Panion is a small company and we do not have the resources to extend beyond this.

Thank you and regards,

Cindy Chiang
Panion & BF Biotech Inc
Phone: (02) 26558218 ext 302
Fax: (02) 26558318
Email: cchiang@pbf.com.tw

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Sent: Monday, August 14, 2006 10:32 PM
To: Cindy Chiang
Cc: Winston Town; rniecestro@keryx.com; tmason@keryx.com; cfaan@bripharm.com; David Kwok; kchan@globoasia.com; khoberman@keryx.com; michaelchiang@pbf.com.tw
Subject: RE: Urgent request for Ferric Citrate API

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To: 'Cindy Chiang'
Cc: 'Winston Town'; Niecestro, Robert [rniecestro@keryx.com]; Mason, Tim [tmason@keryx.com]; cfaan@bripharm.com; 'David Kwok'; kchan@globoasia.com; Hoberman, Ken [khoberman@keryx.com]; michaelchiang@pbf.com.tw
Subject: RE: Urgent request for Ferric Citrate API

Dear Cindy

Thank you for your response and the introduction to BRI. Tim Mason, my Director of API Process Development will be the lead on that project. Please obtain a formal quotation for production of 4 kg.

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Finally, I would greatly appreciate it if you could provide some API from your inventory to start toxicity testing that is related to completing phase 2 requirements. We need to do this before we can enter phase III. Can you check please and advise what might be available?

Best Regards

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Sent: Monday, August 14, 2006 9:26 AM
To: Bennett, William J. [wbennett@keryx.com]; michaelchiang@pbf.com.tw; Hoberman, Ken [khoberman@keryx.com]
Cc: 'Winston Town'; Niecestro, Robert [rniecestro@keryx.com]; Mason, Tim [tmason@keryx.com]; 'Cindy Chiang'; cfaan@bripharm.com; 'David Kwok'; kchan@globoasia.com
Subject: RE: Urgent request for Ferric Citrate API

Dear Bill,

To facilitate your CMC development, I here, under separate email, introduce you to BRI, contents of which are self explanatory. Please find an indicated quotation obtained from Biovectra/BRI in February 2006. If this is in line with your current thinking, we will obtain formal quotation from Biovectra/BRI

Best regards,

Cindy Chiang
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Phone: (02) 26558218 ext 302
Fax: (02) 26558318
Email: cchiang@pbf.com.tw

From: wbennett@keryx.com [mailto:wbennett@keryx.com]
Sent: Wednesday, July 26, 2006 1:20 AM
To: michaelchiang@pbf.com.tw

Cc: Winston Town; cindy chiang; khoberman@keryx.com; rniecestro@keryx.com; tmason@keryx.com
Subject: Urgent request for Ferric Citrate API

Dear Michael

You should receive your payment by wire very shortly -- Ken Hoberman is coordinating.

Once the account is settled, I would like to proceed ASAP on procurement of API.

At our recent meeting with the FDA, they indicated that we will not have fulfilled our Phase 2 requirements with this compound until three studies are performed -- which will require up to 100 kg of API in total. We want to complete this work ASAP since until we complete these Phase 2 requirements, we cannot begin our Phase 3 work.

Would you please tell me if you have API in inventory that you could transfer to us under the cost conditions of the contract? Even if you do not have the full quantity, at least we could start the longer studies.

Finally, further to my note early in the month to Cindy -- I would also like to advance the production of several batches as well with BRI. How would you like to handle these arrangements? Shall I contact BRI directly or would you like us to work jointly on the project?

Thanks and Best Regards

Bill

Exhibit 5
to Declaration of William J. Bennett

From: Clara Faan [mailto:cfaan@bripharm.com]
Sent: Thursday, August 24, 2006 7:00 PM
To: Bennett, William J. [wbennett@keryx.com]
Cc: David Kwok; Winston Town; Cindy Chiang; Mason, Tim [tmason@keryx.com]; Genovesi, Lina [lgenovesi@keryx.com]
Subject: RE: CDA For BRI/Keryx

Hi Bill,

Thanks for your email messages and CDA template. Attached is a copy of the signed CDA. Please kindly return a fully executed copy for my file.

The quotation for manufacturing of 400 Kg Ferric Citrate is also attached. Stephen Ball is the Product Manager at Biovectra. His email address is sball@biovectra.com. Please feel free to contact Stephen if you have any question regarding the manufacturing process and cost. Manufacturing release testing is subcontracted to BRI. The testing cost is $5,000.

Currently, we have about 280g of ferric citrate retention sample in-house from previous production. I am afraid that the quantity is far from your requirement.

BRI has assisted Panion since 2001 on CMC related areas of the ferric citrate project. Should you have any question, please do not hesitate to contact me.

Best regards,
Clara

==========

Clara
Faan

VP Business Development / COO
BRI Biopharmaceutical Research Inc.
101 - 8898 Heather Street
Vancouver, BC, V6P 3S8
Phone: 604-432-9237 (x224)
Fax: 604-432-9239
Email: cfaan@bripharm.com

Exhibit 6
to Declaration of William J. Bennett

From: Cindy Chiang [mailto:cchiang@pbf.com.tw]
Sent: Friday, September 01, 2006 7:29 AM
To: Bennett, William J. [wbennett@keryx.com]
Cc: 'Winston Town (GBA)'; michaelchiang@pbf.com.tw
Subject: RE: Ferric Citrate in Inventory?

Dear Bill,

Thanks for informing us. Panion will not participate in the conference of BRI and Keryx. However, please remember any changes of API or charges to Panion will need to be agreed upon by us. To answer your second question, I've checked the inventory and found out we don't have any quantity in stock.

Best regards,

Cindy Chiang
Panion & BF Biotech Inc
Phone: (02) 26558218 ext 302
Fax: (02) 26558318
Email: cchiang@pbf.com.tw

From: wbennett@keryx.com [mailto:wbennett@keryx.com]
Sent: Monday, August 28, 2006 5:47 AM
To: Cindy Chiang
Cc: Winston Town (GBA); michaelchiang@pbf.com.tw
Subject: Ferric Citrate in Inventory?

Dear Cindy

Thanks for your help in organizing all of this. To cover the specifications and the significance of the different ones, should we conference Panion, BRI and Keryx. What would be your suggestions?

As you can see, BRI has no inventory to speak of. Does Panion have 5 kg which we could either purchase or borrow and return after the production?

Thanks and Best Regards,

Bill

From: Clara Faan [mailto:cfaan@bripharm.com]
Sent: Thursday, August 24, 2006 7:00 PM
To: Bennett, William J. [wbennett@keryx.com]
Cc: David Kwok; Winston Town; Cindy Chiang; Mason, Tim [tmason@keryx.com]; Genovesi, Lina [lgenovesi@keryx.com]
Subject: RE: CDA For BRI/Keryx

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BRI has assisted Panion since 2001 on CMC related areas of the ferric citrate project. Should you have any question, please do not hesitate to contact me.

Best regards,
Clara

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Faan
VP Business Development / COO
BRI Biopharmaceutical Research Inc.
101 - 8898 Heather Street
Vancouver, BC, V6P 3S8
Phone: 604-432-9237 (x224)
Fax: 604-432-9239
Email: cfaan@bripharm.com

Exhibit 7
to Declaration of William J. Bennett

From: Bennett, William J. [wbennett@keryx.com]
Sent: Monday, September 11, 2006 9:50 AM
To: Cindy Chiang; Winston Town (GBA)
Cc: Hoberman, Ken [khoberman@keryx.com]; Mason, Tim [tmason@keryx.com]; michaelchiang@pbf.com.tw
Subject: RE: CDA For BRI/Keryx

Dear Cindy/Winston

Since I am planning a large prep of FeCitrate, I wanted to double-check with you to see if you have any API needs for the next several months. I would be happy to organize prep of any additional material you might need over the next 6 months.

Best Regards

Bill

Exhibit 8
to Declaration of William J. Bennett

-----Original Message-----
From: Clara Faan [mailto:cfaan@bripharm.com]
Sent: Wednesday, October 25, 2006 7:10 AM
To: Bennett, William J. [wbennett@keryx.com]; Clara Faan (BRI); Cindy Chiang
Cc: bobcatw@comcast.net; Daniel Gold; David Kwok (BRI); Winston Town (GBA); michaelchiang@pbf.com.tw
Subject: Re: Draft of proposed specification changes for ferric citrate

Hi Bill,

My apology for the late reply as both David and I are currently away travelling on business.

I understand that BRI's study team is putting together a draft revise specification based on our discussion along with a change control as we speak. A costing prospal is also being put together for the TGA testing.
The costing info should be available later today. I will up-date you later regarding the revise specification.

David and I are available for a t-con next week between Monday to Wednesday late in the afternoon around 4:00 pm EST. Please let me know if this schedule will work for everyone.

Thanks!

Best Regards,
Clara

On
<wbennett@keryx.com> wrote:
> Clara & Cindy
>
> Since we do not have any response to this note, I would like to set up

> a teleconference to discuss these proposed changes to the
> specifications sometime next week as we need to come to agreement
> before finalizing the production at BioVectra
>
> Would you please indicate your availability next week.
> We will have our
> regulatory consultant present as well who can help address any
> regulatory questions. Please indicate what other attendees you would
> like to have from your side.
>
> Thanks & Best Regards
>
> Bill
>
> _____
>
> From: Mason, Tim [tmason@keryx.com]
> Sent: Tuesday, October 17, 2006 11:50 AM
> To: David Kwok (BRI)
> Cc: Clara Faan (BRI); Bennett, William J.
> [wbennett@keryx.com];
> bobcatw@comcast.net; Daniel Gold

> Subject: Draft of proposed specification changes for ferric citrate
>
>
> David,
>
> * Attached is the draft of proposed specification changes
> for ferric citrate as we discussed. Please review as expeditiously as possible so that some changes might be implemented for this production campaign.
>
> * We did not discuss the microbial specifications for ferric citrate. The levels seem very low for an oral dose pharmaceutical and we do not see a regulatory basis for it. According to USP <1111>, 2nd Supplement to USP 29, Aug. 1, the microbial limits for solid dosage forms are 1000 CFU/g for total aerobic count and 100 CFU/g for total yeast and molds. If necessary we can set up a phone conference to discuss this.
>
> * You were going to confirm the water levels from the latest stability samples by TGA using a reduced scan rate to resolve different hydrate levels.
>
> * The table on the mass balance of heavy metals we discussed was in error. The data for the three ferric citrate lots was for the 500 g lots whereas the raw material data was for the 125 kg lot.
> A corrected table is attached. The level of lead was much lower in the
> 125 kg batch lots than in the 500 g lots. Arsenic, cadmium, mercury and lead are below the calculated limits based on NHPD for the 125 kg based lots. Can you provide me with the full ICP scan of the three PharmPro lots (20024, 20025 and 20026)?
>
> Best Regards,
>
> Tim
>
>
>
> Timothy F. Mason
> Director
> API Process Development & Manufacturing
> 750 Lexington, 20th Floor
> New York, NY 10022
> Tel: 212-531-5967
> Fax 212-531-5961
> Mobile: 908-334-0176
> Tmason@keryx.com <mailto:Tmason@keryx.com>
> www.keryx.com

Exhibit 9
to Declaration of William J. Bennett

From: Cindy Chiang (PBF) [mailto:cchiang@pbf.com.tw]
Sent: Monday, July 30, 2007 2:58 AM
To: Mason, Tim [tmason@keryx.com]; Hoberman, Ken [khoberman@keryx.com]
Cc: Bennett, William J. [wbennett@keryx.com]; Levine, Beth [blevine@keryx.com]; michaelchiang@pbf.com.tw; 'Cindy Chiang (PBF)'; 'Michael Stanley'; wtown@globoasia.com; kchan@globoasia.com
Subject: RE:

Dear Tim:

Thank you for the e-mail and the information on Ferric Citrate Drug Product development and informing us that Keryx is preparing to file an amendment of IND 52,868 for the different capsule size and related changes on the drug product which will be used in the upcoming Keryx's 28-day tolerability study. Since the US IND and drug product used in the US studies are now Keryx's responsibility, Panion has no objection. However, under the Keryx-Panion Licensing Agreement, Panion will be the sole provider of the drug substance (active pharmaceutical ingredient, API) for Keryx. As such, Panion shall file a corresponding DMF amendment for the drug substance to support Keryx's IND. We understand that Keryx, with the Panion subcontractor BRI help, has manufactured a new batch of drug substance and have changed some of the specifications. We have asked in our previous correspondence in this matter for the final documents on manufacturing records and changes and have not heard from you since. Therefore, can you please provide us with the final executed batch records and final specifications for the newly manufactured batch so that we can file the updated information to update the DMF on drug substance in order to support Keryx's IND and new studies? Thank you.

Regards,
Cindy Chiang
Panion & BF Biotech Inc
Phone: (02) 26558218 ext 302
Fax: (02) 26558318
Email: cchiang@pbf.com.tw